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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,879	10/12/2005	Terrence R Langford	122123.00004US1	4467

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EXAMINER

DELCOTTO, GREGORY R

ART UNIT PAPER NUMBER

1751

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/552,879

Applicant(s)

LANGFORD, TERRENCE R

Examiner

Gregory R. Del Cotto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/12/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/06, 10/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 14-29 are pending. Claims 1-13 have been canceled. Note that, the preliminary amendment filed 10/12/05 has been entered.

Information Disclosure Statement

Note that, with respect to EP 356,896, EP 470,116, and EP 664,715, these references have not been considered, as indicated in the attached listing of the references, because no statement of relevancy has been provided with these non-English documents. The submission of these references fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language.

Priority

Note that, Applicant has incorrectly claimed priority under 35 USC 119(e) to International Application No PCT/US03/012027 in the preliminary amendment filed 10/12/05. The instant application is a 371 application of PCT/US03/012027 and does not claim priority under 35 USC 119(e) to PCT/US03/012027. 35 USC 119(e) is used to claim priority to US provisional applications. Correction is required.

Claim Objections

Claim 20 is objected to because of the following informalities:

With respect to claim 20, line 2, it is suggested that Applicant delete "paracetic" and insert "peracetic".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high-level" in claims 14, 21, and 27 is a relative term which renders the claim indefinite. The term "high-level" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note that, the Examiner asserts that in the absence of a definition, it would not be clear to one of ordinary skill in the art as to what levels of disinfection fall within and outside the scope of "high-level" as recited by the instant claims. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,443,801) in view of Hitchems et al (US 6,468,953).

Langford teaches a cleansing/sterilizing apparatus which is a transportable apparatus and for inside-outside and sterilization of various complex reusable medical/dental instruments, including but not limited to laparoscopic instruments and dental handpieces. See Abstract. Specifically, Langford teaches filling a wash chamber and soaking the instruments with filtered ozonated water agitated by a peristaltic pump to denature any protein contaminants; draining the soak water by injecting sterile oxygen gas or sterile inert gas; washing the instruments with detergent in warm filtered water; draining the wash water by injecting sterile oxygen gas or sterile inert gas; rinsing the instruments with filtered ozonated water agitated by the peristaltic pump to sterilize all surfaces inside and out and to flush any remaining bio-debris; and draining the rinse water. The rinse cycle may be repeated multiple times. See column 21, lines 1-50.

Langford et al do not teach the specific amount of ozone in the water, the use of a chemical sterilizing agent such as peracetic acid or a method of cleaning and sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims.

Hitchems et al teach the formation of antimicrobial solutions formed by ozonating a liquid containing organic precursor molecules. After ozonation is complete, the ozonated liquid may be diluted with water or other solvent to form a use solution for

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contacting and cleaning a microbially contaminated surface or other medium. See Abstract. Additives to the solution may include antimicrobial agents such as peroxygen-type disinfectants including peracetic acid, etc. See column 11, lines 30-65. The ozonated solution has a water to a water/ozonated solution ratio of between 1 and 100. See column 4, lines 30-55.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use water having the same volume of ozone as recited by instant claim 17, with a reasonable expectation of success, because Hitchems et al teach the use of ozone containing liquids having the same amount of ozone as recited by the instant claims for sterilizing medical instrument surfaces and further, Langford et al teach using ozone containing liquids for sterilizing medical instruments in general.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an antimicrobial agent such as peracetic acid in the ozone rinse step in the process of sterilizing endoscopes taught by Langford et al, with a reasonable expectation of success, because Hitchems et al teach the use of peracetic acid as an antimicrobial agent in a similar process using ozone as a cleaning/disinfecting agent and further, the use of antimicrobial agents such as peracetic acid would be desirable because of the additional disfection/sterilization properties provided by the use of peracetic acid in combination with ozone.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to sterilize a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as

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recited by the instant claims, with a reasonable expectation of success, because the broad teachings of Langford in combination with Hitchems et al suggest sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims.

Claims 21-29 are rejected under 35 U.S.C. 102(a) as being anticipated by WO02/32467.

'467 teaches an apparatus for cleaning medical equipment comprising a supply of filtered water, a supply of ozonated water containing a predetermined concentration of water and means for delivering first a flow of filtered water over the surfaces of the equipment to be cleaned for a predetermined time followed by a flow of ozonated water over said surfaces for a predetermined time to disinfect the surfaces. See Abstract. The ozonated water is de-ionized prior to ozonating to the predetermined concentration. In the system, unozonated water was pumped through the system for 10 minutes and then ozonated water was pumped through the system for 6 minutes which achieves a high level disinfection. See page 6, lines 1-15. After the cycle, rinse water and ozonated water may also be flowed over the outer surface of the endoscopes to disinfect these as well. See page 7, lines 10-35. The apparatus is comprises a meanse for filtering the tap water used in the process to provide a supply of filtered water. See claim 12. '467 discloses the claimed invention with sufficient specificity to constitute anticipation.

Accordingly, the teachings of '467 anticipate the material limitations of the instant claims.

Response to Arguments

This is responsive to Applicant's arguments filed 10/12/05. With respect to Langford, Applicant states that Langford does not disclose or suggest an "overkill rinse" of an already cleaned and sterilized item. In response, note that, the Examiner maintains that the endoscopes may be rinsed with ozonated water multiple times (See column 21, lines 45 to 50 of Langford) which would suggest an "overkill rinse" of an already cleaned and sterilized item as recited by the instant claims.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.


Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas McGinty can be reached on (571) 272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gregory R. Del Cotto
Primary Examiner
Art Unit 1751

GRD
October 27, 2006